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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,314	05/17/2005	David Wallach	WALLACH33	6672
1444 7590 01/07/2011 Browdy and Neimark, PLLC 1625 K Street, N.W. Suite 1100 Washington, DC 20006				
EXAMINER				
SWOPE, SHERIDAN				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,314

Applicant(s)

WALLACH ET AL.

Examiner

SHERIDAN SWOPE

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 106-108, 110 and 111 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 106-108, 110, and 111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' filing of December 13, 2010, in response to the action mailed August 11, 2010, is acknowledged. It is acknowledged that Claim 109 has been cancelled and Claims 106-108 and 111 have been amended. The invention under prosecution is directed to an isolated NF- κ B inducing kinase (NIK) polypeptide that binds to a common gamma chain (*cyc*). Claims 106-108, 110, and 111 are pending and are hereby considered.

Priority

As stated in the prior action, because the Examiner failed to see that Israel 14927 or 152183 disclosed SEQ ID NO: 18 or 19, the priority date granted for the instant claims is April 15, 2003, the filing date of PCT/IL03/00317. Applicants' assertion that Israel 14927 and 152183 disclosed SEQ ID NO: 18 and 19 is acknowledged. However, since Applicants' have not directed the Examiner to where, in Israel 14927 and 152183, SEQ ID NO: 18 and 19 are disclosed, said assertion cannot be verified.

Claim Rejections - 35 USC § 101

Rejection of Claims 106-108 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 8 of US Application 12/166,110 is withdrawn because Claim 8 of US Application 12/166,110 has been cancelled.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 106-108, 110, and 111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

Rejection of Claims 106-108, 110, and 111, because the phrase “residues 640 to 720 of SEQ ID NO: 19” renders the claim indefinite, as explained in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments. The specification at page 20, lines 9-10 (paragraph [0071]) clearly discloses that a domain of NIK, responsible for *cyc* binding, comprises 81 amino acid residues from the C-terminus of NIK (from residue 624 to 947) (i.e., our SEQ ID NO: 19), named NIK640-720 (our SEQ ID NO: 18). This indicates that SEQ ID NO: 18 (residues NIK640-720) is located within SEQ ID NO: 19 (residues 624 to 947). This supports element (c) of claims 106 and 107 that recites “a fragment of (a) or (b) that retains the ability to bind *cyc* and includes residues 640 to 720 of SEQ ID NO: 19”, as residues “640 to 720” fall within residues 624 to 947 of SEQ ID NO: 18. Further, as disclosed in the specification, “640 to 720 of SEQ ID NO: 19” is clearly encompassed by residues 624 to 947 (SEQ ID NO: 19). As such, the objected language is not inconsistent with the teachings in the disclosure.

These arguments are not found to be persuasive for the following reasons. The Examiner finds Applicants’ argument to be confusing. It is assumed that Applicants’ argument means the following: (i) full length NIK is 947 residues, (ii) the application does not disclose said full-length NIK, (iii) residues 640-720 of said full length NIK is as set forth by SEQ ID NO: 18, (iv) residues 640-720 of said full length NIK, as set forth by SEQ ID NO: 18, is the region of NIK that binds *cyc*, (v) residues 624-947 of said full length NIK is as set forth by SEQ ID NO: 19, and (vi) SEQ ID NO: 18 is comprised within SEQ ID NO: 19. Based on these assumptions, the phrase “residues 640 to 720 of SEQ ID NO: 19” renders Claims 106, 107, and 111 indefinite because SEQ ID NO:

19 has only 324 residues. It is suggested that Applicants' representative contact the Examiner to discuss how to overcome this rejection.

Rejection of Claims 106-108, 110, and 111 because the phrase "the carboxyl group" renders the claim indefinite is withdrawn. It is acknowledged that Applicants have clarified that said phrase encompasses carboxyl groups present on the lateral chains of amino acid moieties and on the C-terminus. Nonetheless, see the rejection below for lack of antecedent basis.

Rejection of Claim 111, because the phrase "860 of human NIK", without reference to a specific sequence, renders the claim indefinite is maintained. Applicants did not comment on this rejection.

Claims 106-108, 110, and 111 are rendered indefinite for improper antecedent usage as follows.

For Claims 106a, 106b, 106c, 107a, 107b, 107c, 108c, and 108d, "the same *cyc* protein" lacks antecedent basis. Claims 110 and 111, as dependent claims, are rendered indefinite for the same reasons.

For Claims 106c, 107c, and 108d, the phrase "the carboxyl group" should be corrected to "a carboxyl group".

Any subsequent rejection based, on clarification of the above phrases and terms, will not be considered a new ground for rejection.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Rejection of Claims 106-108 under 35 U.S.C. 112, first paragraph/enablement, for reasons explained in the prior action, is maintained.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments. These arguments are not found to be persuasive for the reasons following each argument.

(A) The claims have been amended to "a polypeptide having at least 95% identity with SEQ ID NO: 19" (or SEQ ID NO: 18) and to further specify that the polypeptide binds to the same *cyc* protein that SEQ ID NO: 19 (or SEQ ID NO: 18) binds to. With respect to the fragments embodiment [embodied], the claims have been similarly amended to specify binding to the same *cyc* protein that the whole [SEQ ID NO: 18 or 19] binds to.

(A) Reply: It is acknowledged that the claims have been so amended and that the genera of polypeptides having 95% identity to SEQ ID NO: 18 or 19, with a specific functional limitation, would not represent undue experimentation to make and use. However, recitation of "binds to the same *cyc* protein that SEQ ID NO: 19 (or SEQ ID NO: 18) binds to" is not recitation of a specific functional limitation. As explained in the prior action, the specification does not establish the structure of the genus of polypeptides having any *cyc* function. The specification also does not establish the structure of the genus of polypeptides having any *cyc* function which bind to SEQ ID NO: 18 or 19. Identifying any protein, having any structure and any *cyc* function, wherein the protein binds to SEQ ID NO: 18 or 19 represents undue experimentation. Thus, identifying any variant or fragment of SEQ ID NO: 18 and 19 that binds to any said above identified *cyc* protein also represents undue experimentation.

(B) The specification provides examples for the binding of SEQ ID NO: 18 and 19 to *cyc*.

(B) Reply: As explained in the prior action, it is acknowledged that the specification is enabling for the polypeptides of SEQ ID NO: 18 and 19, which bind to the human bone marrow *cyc* protein. The Examiner fails to see that the specification discloses that the polypeptides of SEQ ID NO: 18 and 19 bind to any other *cyc* protein.

For these reasons and those explained in the prior action, rejection of Claims 106-108 under 35 U.S.C. 112, first paragraph/enablement, is maintained.

Written Description

Rejection of Claims 106-108 under 35 U.S.C. 112, first paragraph/written description, for reasons explained in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the same arguments presented above. These arguments are not found to be persuasive for the reasons presented above.

For these reasons and those explained in the prior action, rejection of Claims 106-108 under 35 U.S.C. 112, first paragraph/ written description, is maintained.

Claims 106-108, 110, and 111 are herein rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. Claims 106a, 106b, 106c, 107a, 107b, 107c, 108c, and 108d, as amended, introduce the limitations of "the same *cyc* protein that SEQ ID NO: 19 (or SEQ ID NO: 18) binds to". The specification fails to describe said limitations and, thus, Claim 106-108, and dependent Claims 110 and 111 are rejected under 35 U.S.C. 112, first paragraph, for introducing New Matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of Claims 106 and 107 under 35 U.S.C. 102(b) as being anticipated by Wallach et al, 1997, as explained in the prior action, is maintained.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments. These arguments are not found to be persuasive for the reasons following each argument.

(A) It appears that prior art example 5 [of Wallach et al] teaches SEQ ID NO. 19. However, Wallach et al does not disclose Applicants' use.

(A) Reply: The instant claims are directed to a product, not a method or use. Thus, this argument is not relevant to the instant claims.

Any functional characteristic of SEQ ID NO: 19, i.e., binding, are inherent to the polypeptide disclosed by Wallach et al, which is SEQ ID NO: 19 herein.

(B) Wallach et al does not disclose fragments and variants of SEQ ID NO: 19.

(B) Reply: It is acknowledged that Wallach et al does not disclose fragments and variants of SEQ ID NO: 19. However, the claims are not limited to fragments and variants of SEQ ID NO: 19 and encompass the peptide of SEQ ID NO: 19, which is disclosed by Wallach et al.

(C) Claims 106 and 107 have been amended to delete sub-paragraph (a), i.e., the polypeptide of SEQ ID NO: 19. Thus, the claims no longer claim just SEQ ID NO: 19, but instead only the

variants and fragments thereof. In doing so, the present amendment obviates the rejection, because Wallach et al., 1997 (IDS; WO9737016) does not disclose the fragments, variants, etc. as claimed.

(C) Reply: It is acknowledged that Claims 106 and 107 have been amended to delete prior sub-paragraph (a). However, the genus of polypeptides having at least 95% identity with SEQ ID NO: 19, as recited in Claims 106a and 107a encompasses SEQ ID NO: 19.

For these reasons and those explained in the prior action, rejection of Claims 106 and 107 under 35 U.S.C. 102(b) as being anticipated by Wallach et al, 1997, is maintained.

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection(s) based on amendment or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN SWOPE whose telephone number is 571-272-0943. The examiner can normally be reached on 11a-7:30p7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652